

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**
4 **PANCREAS TRANSPLANTATION SERVICES**
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6 (By authority conferred on the ~~Certificate of Need~~CON Commission by Section 22215 of Act No. 368 of
7 the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as
8 amended, being Sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
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10 **Section 1. Applicability**
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12 Sec. 1. (1) These standards are requirements for the approval and delivery of services for all
13 projects approved and Certificates of Need issued under Part 222 of the Code which involve pancreas
14 transplantation services.
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16 (2) Pancreas transplantation is a covered clinical service for purposes of Part 222 of the Code.
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18 (3) The Department shall use sections 3 and 5, as applicable, in applying Section 22225(1) of the
19 Code, being Section 333.22225(1) of the Michigan Compiled Laws.
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21 (4) The Department shall use Section 4, as applicable, in applying Section 22225(2)(c) of the
22 Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
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24 **Section 2. Definitions**
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26 Sec. 2. (1) As used in these standards:

27 (a) "Certificate of Need Commission" or "CON Commission" means the Commission created
28 pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

29 (b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et
30 seq. of the Michigan Compiled Laws.

31 (c) "Department" means the ~~state agency known as the~~ Michigan Department of Community
32 Health (~~MDCH~~).
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34 (d) "Implementation plan" means a plan that documents how a proposed pancreas transplantation
35 service will be initiated within the time period specified in these standards or the ~~Certificate of Need~~CON
36 rules. At a minimum, the implementation plan shall identify: (i) each component or activity necessary to
37 begin performing the proposed pancreas transplantation service including but not limited to the
38 development of physical plant requirements such as an intensive care unit capable of treating immuno-
39 suppressed patients, equipment acquisition(s), and recruitment and employment of all physician and
40 support staff; (ii) the time table for completing each component or activity specified in subsection (i); and
41 (iii) if the applicant has previously been approved for a pancreas transplantation service where either the
42 ~~Certificate of Need~~CON expired or the service did not perform a transplant procedure during any
43 consecutive 12-month period, what changes have or will be made to ensure that the proposed service
44 can be initiated and provided on a regular basis.

45 (e) "Initiate" or "implement" for purposes of these standards, means the performance of the first
46 transplant procedure. If the ~~Certificate of Need~~CON rules do not authorize a ~~Certificate of Need~~CON
47 review standard to define the term of the certificate, the term shall be as provided in Rule 325.9403(1)
48 and (2). If the ~~Certificate of Need~~CON rules do authorize a standard to define the term of a certificate, the
49 term shall be 18 months or the extended period established by Rule 325.9403(2), if authorized.

50 (f) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility
51 authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital
52 with multiple sites, the location of each separate and distinct inpatient unit of the health facility as
53 authorized by license and listed on that licensee's certificate of licensure.

54 (G) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT.
620, 1396R-6 AND 1396R-8 TO 1396V.

(gH) "OPO" or "Organ Procurement Organization" means an organ procurement organization as defined by Title 42, Part 486.302.

(hI) "OPTN" or "Organ Procurement and Transplantation Network" means the organization contracted by the federal Department of Health and Human Services to operate the organ procurement and transplantation network.

(iJ) "Survival rate" means, for purposes of these standards, the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(2) The definitions of Part 222 shall apply to these standards.

Section 3. Requirements for approval -- all applicants

Sec. 3. (1) An applicant proposing to perform a pancreas transplantation service shall demonstrate that it offers all of the following services or programs on site:

- (a) operating rooms;
- (b) anesthesiology;
- (c) microbiology and virology laboratory;
- (d) continuous availability, either on-site or on-call, of diagnostic imaging services including: (i) CT scanning, (ii) magnetic resonance imaging, and (iii) nuclear medicine;
- (e) continuous availability, either on-site or on-call, of a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology;
- (f) dialysis;
- (g) infectious disease;
- (h) inpatient-outpatient social work;
- (i) inpatient-outpatient psychiatry/psychology;
- (j) clinical research;
- (k) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization, either on-site or through written agreement;
- (l) other support services, as necessary, such as physical therapy and rehabilitation medicine;
- (m) continuous availability of anatomic and clinical pathology and laboratory services including clinical chemistry, immuno-suppressive drug monitoring, and tissue typing;
- (n) continuous availability of red cells, platelets, and other blood components;
- (o) an established organ donation protocol, with brain death protocol, consistent with applicable Michigan law; and

(p) a written agreement with Michigan' s federally designated organ procurement organization (OPO) to promote organ donation at the applicant hospital(s).

(2) An applicant must provide, at the time the ~~Certificate of Need~~CON application is submitted, an implementation plan for the proposed pancreas transplantation service.

(3) An applicant for a pancreas transplantation service shall project a minimum of 12 pancreas transplantation procedures annually in the second 12 months of operation following the date on which the first pancreas transplant procedure is performed and annually thereafter.

(4) An applicant proposing to provide a pancreas transplantation service shall demonstrate that it offers all of the following services or programs:

- (a) continuous availability, either on-site or on-call, of angiography;
- (b) an intensive care unit with 24 hour per day on-site physician coverage;
- (c) an on-site renal transplant service that has performed a minimum of 80 kidney transplants in the 2 most recent 12 month periods for which verifiable data are available; and
- (d) ophthalmology retinal eye service availability, either on site or on call.

(5) AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 4. Project delivery requirements -- terms of approval for all applicants

Sec. 4. (1) An applicant shall agree that, if approved, the services shall be delivered in compliance with the following terms of ~~Certificate of Need~~CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the pancreas transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable:

(i) The applicant shall perform the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall comply with applicable OPTN and Medicare requirements.

(iii) The applicant shall have patient management plans and protocols that include the following: (A) therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service; and (C) long-term management and evaluation, including education of the patient, liaison with the patient' s attending physician, and the maintenance of active patient records for at least five (5) years.

(iv) The applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(v) An applicant shall actively participate in the education of the general public and the medical community with regard to pancreas transplantation, and will make organ donation literature available in public areas of the institution.

(vi) The applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed pancreas transplantation service.

(vii) The applicant' s education and research program related to pancreas transplantation shall be subject to external peer review.

(viii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall

participate in state and national transplantation registries applicable to the pancreas transplantation service.

(ix) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, patient survival rates at both 12 and 24 months following the transplant procedure, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(x) The applicant, to assure that the pancreas transplantation service will be utilized by all segments of the Michigan population, shall:

(A) not deny the services to any individual based on ability to pay or source of payment;

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and

(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xi) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(XII) AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(d) An applicant shall agree to establish and maintain all of the following:

(i) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed pancreas transplantation service;

(ii) organ preservation capability;

(iii) an organized 24-hour transport system for transportation of organs, donors, and blood serum;

(iv) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;

(v) a laboratory with immunosuppression assay results available on the same day, as appropriate;

(vi) an immunologic monitoring laboratory;

(vii) a specialized inpatient pancreas transplantation unit or a combined inpatient renal and extrarenal transplantation unit;

(viii) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;

(ix) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients;

(x) a multi-disciplinary transplant recipient evaluation committee;

(xi) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization, either operated on-site or through written agreement;

(xii) insulin, C-peptide, glycosylated hemoglobin assays;

(xiii) glucometer glucose assay availability; and

(xiv) electromyography.

(e) An applicant shall agree that the pancreas transplantation service shall be staffed and provided by at least the following:

(i) a transplant team leader and coordinator;

(ii) transplant surgeons and physicians experienced with renal transplantation in diabetics;

(iii) surgeons with demonstrated proficiency in major pancreatic surgery;

- (iv) both adult and pediatric surgeons, as appropriate;
- (v) qualified adult and pediatric, as appropriate, transplant surgeon(s) and transplant physician(s). For purposes of evaluating subsection (v), the Department shall consider it prima facie evidence as to the qualifications of the surgeon(s) and physician(s) if both the kidney and pancreas transplantation programs are approved by and a member in good standing of the OPTN;
- (vi) a pathologist capable of diagnosing pancreatic rejection; and
- (vii) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of transplant patients, and managing immuno-suppressed patients.
- (f) Compliance with the Uniform Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the Michigan Compiled Laws.
- (2) An applicant must demonstrate pancreatic graft survival rates at one year and two years after transplantation of no less than the national average survival rate for the most recent year for which data is published by the OPTN.
- (3) The agreements and assurances required by this section, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 5. Documentation of projections

Sec. 5. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 6. Effect on prior ~~Certificate of Need~~CON review standards; comparative reviews

Sec. 6. (1) These ~~Certificate of Need~~CON review standards supersede and replace the CON Review Standards for Pancreas Transplantation Services approved by the ~~Certificate of Need~~CON Commission on ~~October 26, 1993~~SEPTEMBER 26, 2002 and effective on December ~~1823, 1993~~2002.

- (2) Projects reviewed under these standards shall not be subject to comparative review.